

The Rapid Evolution of Vaginal Mesh Delivery Systems for the Correction of Pelvic Organ Prolapse, Part I: Clinical Data

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Last fall, during a meeting of the ACOG Gynecologic Practice Committee, an FDA official was made aware of the current controversy surrounding vaginal mesh placement to correct pelvic organ prolapse. Three weeks later, on October 20th, the FDA issued a public health notification entitled “Serious Complications Associated with Transvaginal Placement of Surgical Mesh in Repair of Pelvic Organ Prolapse and Stress Urinary Incontinence.”¹ This document made reference to “over 1,000 reports from nine surgical mesh manufacturers of complications associated with [vaginal] surgical mesh” and went on to list specific complications, such as mesh erosion through the vaginal epithelium, infection, pain, urinary problems, and prolapse recurrence.

Apparently, providing an estimate of the rates at which these complications have been occurring was beyond the scope of this FDA notification, because the overall number of mesh procedures that had been performed during the period in question was not included.

This FDA publication has created quite a stir in our field, prompting some individuals

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(especially patients and attorneys) to form negative opinions about vaginal mesh use. These negative opinions are also shared by a subset of gynecologic surgeons who have had to treat mesh-related complications. Often, the surgeons who wind up treating these complications have little or no experience with implantation of the mesh. As a result, there seem to be 2 distinct “factions” developing among gynecologic surgeons: those who never use transvaginal mesh and who only see the complications of these devices, versus those who routinely use the transvaginal mesh delivery systems as one of their tools to correct prolapse. Convincing arguments can be made “for” and “against” use of vaginal mesh delivery systems, with both sides unencumbered by data.

In reality, no “perfect” transvaginal surgical approach to prolapse repair has yet been described. The high failure rates associated with “traditional” repairs (ie, those incorporating only suture and native tissue) have long been recognized, and, except for mesh erosion, the very complications mentioned in the FDA notification have been described for “traditional” repairs as well.^{2,3} Regrettably, the so-called mesh “kits” have evolved so rapidly that new generations of these products have been marketed prior to publication of data regarding prior generations. (The evolution of the commercially available vaginal mesh delivery systems can be traced back much like a “family tree” [Figure].)

Furthermore, most of the peer-reviewed literature about these products has been found in the form of uncontrolled case series, usually from a single center. Now more than ever, the gynecologic surgeon must take on the role of

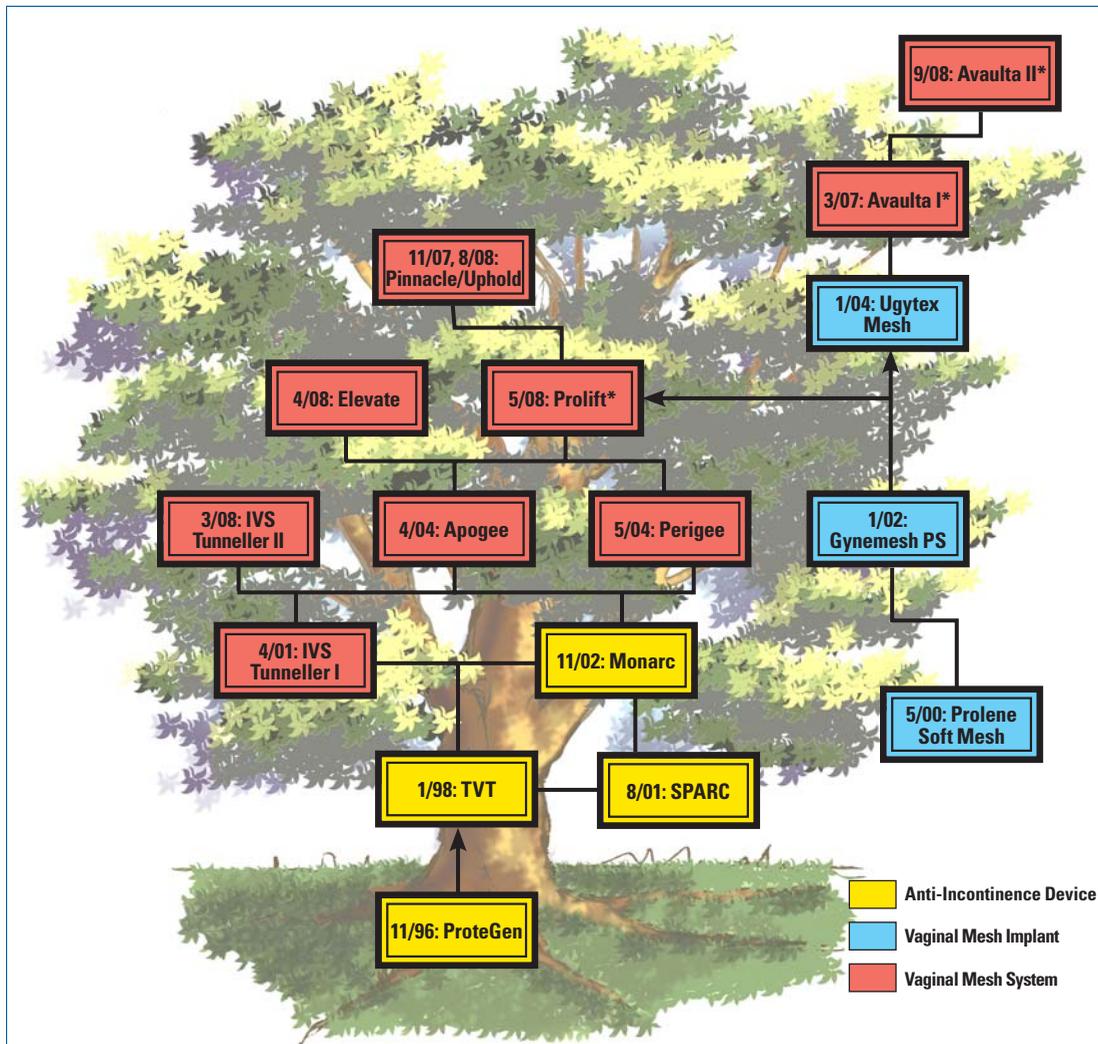


FIGURE. Family Tree of Transvaginal Mesh Systems.

*Products available in the United States prior to these 510(k) approval dates.

gatekeeper by choosing to use these products only when they make sense for patients on a case-by-case basis. In order to do so, the surgeon must be aware of the nuances of the various devices and their peer-reviewed data.

CLINICAL DATA ON CURRENTLY AVAILABLE VAGINAL MESH SYSTEMS

There are currently 7 mesh systems that have been granted 510(k) approval for the correction of pelvic organ prolapse (Table). The following information on these systems was derived from a search of both the MEDLINE and PubMed databases up to January 1, 2009. Only peer-reviewed publications were included in this review. Abstracts presented at scientific meetings were excluded from evaluation.

Perigee/Apogee Vault Suspension System

The Perigee system (American Medical Systems, Minnetonka, MN) is designed to treat anterior vaginal wall defects via 4 side-specific transobturator trocars, while the Apogee system (American Medical Systems, Minnetonka, MN) is designed to treat posterior and apical vaginal wall defects using 2 side-specific trocars passed to the level of the ischial spine via the ischiorectal fossa. Both products may be used either with a polypropylene mesh or a porcine dermal graft.

Nguyen et al randomized 74 patients to be treated either with Perigee or with anterior colporrhaphy.⁴ Objective anatomic cure was defined as POP-Q stage ≤ 2 at a minimum of 1 year after surgery. Cure rates were 55% for the anterior colporrhaphy group and 89% for the Perigee group

TABLE. Vaginal Mesh Systems

	IVS TUNNELLER	PERIGEE/APOGEE	PROLIFT	AVAULTA	PINNACLE	UPHOLD	ELEVATE
Prolapse indications*	Anterior Posterior Apical	Anterior Posterior	Anterior Posterior Apical	Anterior Posterior Apical possible	Anterior Apical	Anterior Apical	Posterior Apical
Material	Type III polypropylene	Type I polypropylene or porcine dermis	Type I polypropylene	Type I polypropylene +/- acellular collagen barrier	Type I polypropylene	Type I polypropylene	Type I polypropylene or porcine dermis both with self- fixating tips to the sacrospinous ligament
Introducer	1 metal trocar used for anterior and posterior placement	Side-specific, compartment- specific metal trocars	1 metal trocar with flexible retrieval device	Compartment- specific metal trocar with InSnare flexible retrieval device	Capio	Capio	Metal trocar designed for attaching mesh to sacrospinous ligament
Transobturator placement	Y	Y	Y	Y	N	N	N
Anchor points	Anterior: 2 transobturator arms Posterior: 1 arm through levator muscles	Anterior: 4 transobturator arms Posterior: 1 arm through levator muscles	Anterior: 4 transobturator arms Posterior: 1 arm through sacrospinous ligament	Anterior: 4 transobturator arms Posterior: 2 arms through either levator muscles or sacrospinous ligament 2 arms through perineal body	2 arms through sacrospinous ligament 2 arms attached to ATFP	2 arms through sacrospinous ligament	2 arms through sacrospinous ligament

* As per product information from manufacturer
ATFP: Arcus tendineus fascia pelvis

(*P*=0.02). Subjective improvements in prolapsed symptoms, lower urinary tract symptoms, and defecatory dysfunction were significantly better in the Perigee group, as well. There were no cases of persistent groin or buttock pain, and dyspareunia rates were not significantly different between the anterior colporrhaphy and Perigee groups. The mesh erosion rate was 5%, and all erosions were successfully treated in an office setting with local excision and vaginal estrogen.

There have been 2 retrospective cohort studies published regarding the Apogee and Perigee systems. Gauruder-Burmester et al followed 48 women treated with Apogee and 72 treated with Perigee postoperatively for ≥1 year.⁵ Of the 120 women in both groups, 93% were anatomically ‘cured’ at 1 year, defined as postoperative leading edge of prolapsed ≥1 cm proximal to the hymen. Subjective results were not collected via validated tools. The overall rate of mesh erosion was not reported, but 3% of the patients experienced vaginal erosions requiring surgical revision in the operating room.

Abdel-Fattah et al followed a total of 70 patients—32 patients treated with Perigee, 30 patients treated with Apogee, and 8 patients treated with both devices.⁶ The follow-up period ranged from 4 to 22 months (mean, 8 months), and objective anatomic success was not clearly defined or stated. Subsequent symptomatic prolapse occurred in the opposite compartment in 25% of the Perigee group and 10% of the Apogee group. No subsequent prolapse occurred during the study period among patients who received both devices. Vaginal erosion rates were 6.25%, 10%, and 12.5% in the Perigee, Apogee, and combined groups respectively, and all of these erosions were treated surgically. Intraoperative complications included 1 rectal injury (during dissection), and 1 hemorrhage of more than 400 mL in the combined group.

Gynecare Prolift Pelvic Floor Repair System

The Gynecare Prolift system (Ethicon Women’s Health and Urology, Somerville, NJ) contains a metal trocar with a flexible mesh retrieval device

designed to be passed through the obturator foramen to correct an anterior vaginal wall defect, or through the sacrospinous ligament via the ischioanal fossa to correct concomitant posterior and apical vaginal wall defects. The Gynecare Prolift polypropylene mesh is available as a 4-armed anterior implant, a 2-armed posterior implant, or a 6-armed combined implant.

In a cadaveric study, distances between major nerves and vessels and the paths of the Gynecare Prolift cannulas were measured.⁷ Properly-placed anterior cannulas passed 3.2 cm to 3.5 cm medial to the obturator neurovascular bundle, and 2.0 cm to 2.2 cm medial to the ischial spine. Properly-placed posterior trocars passed 0.5 cm to 1 cm medial to the pudendal nerve and vessels, and 0.5 cm to 1 cm lateral to the rectum as they passed through the sacrospinous ligament.

The Nordic Transvaginal Mesh Group followed a cohort of 232 patients treated with either the anterior, posterior, or total Gynecare Prolift procedure for at least one year.⁸ Objective anatomic success rates (defined as POP-Q stage ≤ 2) were 79% and 82%, respectively, for patients treated with either the anterior or posterior system alone. When performing the combined procedure, anatomical success rates were 81% in the anterior compartment, and 86% in the posterior compartment. Subjective improvements were seen within each group with respect to validated measures: the Incontinence Impact Questionnaire and the Urogenital Distress Inventory. Intraoperative complications included 2 patients with blood loss of greater than 500 mL, and 9 patients (3.4%) with bladder or rectal perforations. Groin or buttock pain occurred in 5 patients (2.2%), and vaginal erosions occurred in 26 patients (11%). Of those 26 erosions, 7 required surgical intervention.

Six other observational studies have been published evaluating Gynecare Prolift—only one with a follow-up period of ≥ 12 months.⁹⁻¹³ Objective anatomic success rates (defined as POP-Q stage ≤ 2) were between 81% and 100%, and follow-up intervals ranged between 2 and 11 months. These studies reported erosion rates between 0% and 20%.

Avaulta Support System

The Avaulta system (C.R. Bard, Covington, GA) utilizes compartment-specific trocars with a flexible InSnare retrieval device to be passed anteriorly through the obturator foramen, or posteriorly through the ischioanal fossa. This system has 2

additional distal posterior arms, designed to be attached bilaterally to the junction of the bulbocavernosus and transverse perineal muscles. The 4-armed anterior and 4-armed posterior polypropylene mesh is available with or without an acellular collagen barrier. There are no peer-reviewed publications regarding this system.

Pinnacle Pelvic Floor Repair Kit/Uphold Vaginal Support System

The Pinnacle and Uphold systems (Boston Scientific Corp., Natick, MA) utilize the Capiro Suture Capturing Device (Boston Scientific Corp., Natick, MA) to attach mesh placed in the anterior compartment to the sacrospinous ligament, therefore requiring no trocar passes. The Capiro, initially called the Laurus needle driver (ND-260, Laurus Medical Corporation, Irvine, CA), was first described in 1997 as a tool to perform the sacrospinous ligament vault suspension.¹⁴ The Pinnacle (used in post-hysterectomy patients) is comprised of a 4-armed trapezoidal-shaped mesh designed to wrap around the vaginal apex toward the posterior compartment. The Uphold mesh is double-armed with a length of 4 cm, and is designed to repair combined apical/anterior defects while leaving the uterus in place. There are no peer-reviewed publications regarding either of these systems.

Elevate Prolapse Repair System

The Elevate system (American Medical Systems, Minnetonka, MN) is designed to correct concomitant posterior and apical vaginal defects via a single posterior vaginal incision. It utilizes a trocar with a self-fixating tip to attach either a double-armed polypropylene mesh or porcine dermal graft to the sacrospinous ligament. There are no peer-reviewed publications regarding this system.

COMPLICATIONS

The largest case series reporting intraoperative complication rates reported only 2 vascular injuries out of 289 (0.7%) patients treated with Prolift, Apogee, or Perigee.⁶ The first of these involved injury of the right internal pudendal artery while passing the posterior Prolift trocar. The second injury was of the left vaginal artery and right uterine artery during an anterior Prolift procedure. Multiple case reports have been published describing pelvic/vaginal hematomas following mesh system applications, with management strategies consisting of conservative management, surgical evacuation, and radiologic arterial embolization.¹⁵⁻²⁰

Mesh erosion through the vaginal epithelium is another commonly cited complication. Erosion rates range between 0% and 20%, many of which can be treated simply via local excision in an office setting.^{4-11,21,22} This rate is comparable to the typical erosion rate of 3.4% associated with an abdominal sacral colpopexy reported by Nygaard et al.²³

Chronic postoperative pain is perhaps the most worrisome complication associated with vaginal mesh delivery systems. The publication of the largest clinical series of mesh systems reported buttock pain in 5.2% and dyspareunia in 4.5%; however no mention was made of the prevalence of pain or dyspareunia preoperatively.⁶ A recent meta-analysis that included both peer-reviewed publications and abstracts presented at scientific meetings reported rates of dyspareunia between 1.5% and 3%.²⁴

With the various mesh systems now described, look for the May 2009 issue of *The Female Patient* for Part II of this article, "Clinical Recommendations for Vaginal Mesh Systems."

NOTE: Additional content pertaining to this article can be seen online at www.femalepatient.com, including a brief history of surgical mesh and details on the 510(k) submissions process for vaginal mesh systems.

Dr Littman reports no actual or potential conflicts of interest in relation to this article. Dr Culligan reports that he serves as a consultant to Intuitive Surgical, Inc; American Medical Systems; C.R. Bard, Inc., Boston Scientific Corp.; and Ethicon, Inc.; he is a speaker for Intuitive Surgical, Inc.; C.R. Bard, Inc.; and Boston Scientific Corp. He receives research grants from C.R. Bard, Inc. and Boston Scientific Corp; and he is a preceptor for Intuitive Surgical, Inc.

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A BRIEF HISTORY OF SURGICAL MESH

General surgeons have long debated the benefits of incorporating mesh material into abdominal hernia repairs. Those debates were largely put to rest following the publication of a large randomized trial regarding the subject in the

year 2000.¹ This trial reported significantly higher hernia recurrence in those not receiving mesh (43% versus 24%). No such definitive literature yet exists within the field of gynecology.

In 1996, Julian published the first randomized trial involving vaginal mesh placement to

TABLE 1. Medical Device Classification and Premarket Notification 510(k) Provision¹⁰

The FDA classifies medical devices into 3 categories based on their perceived risk:

- Class I devices are perceived to have minimal risk, and include vastly diverse products such as surgical gloves and mesh delivery trocars such as those used in some mesh systems. Clinical trials are not required by the FDA before their introduction into the marketplace.
- Class II medical devices contain a moderate amount of risk and include vaginal mesh and laparoscopic instruments. To reach the general market, the device manufacturer must provide FDA documentation that the device is “safe and efficacious,” which is performed through either premarket clinical studies, or the 510(k) premarket exemption.

- Class III devices include those judged to pose the highest potential risk, and include devices such as pacemakers and coronary stents. This device category, which comprises about 10% of all medical devices, requires premarket clinical trials to be presented to the FDA.

To qualify for the 510(k) exemption, a manufacturer must demonstrate to the satisfaction of the FDA that its device is “substantially equivalent” to a predicate device already on the market. Compared to the predicate device, the novel device may have different technological characteristics; however, it must theoretically be just as safe and have the same intended use. Ultimately, however, no clinical data are required.

TABLE 2. 510(k) Submissions of Vaginal Mesh Systems

YEAR	COMPANY	PRODUCT	PREDICATE DEVICE
4/4/01	Tyco Healthcare Group, L.P.	IVS Tunneller	1. TVT
4/22/04	American Medical Systems	AMS Apogee Vault Suspension System	1. AMS SPARC Sling System 2. AMS Monarc Sling System 3. AMS BioArc 4. AMS Large Pore Polypropylene Mesh 5. IVS Tunneller
5/17/04	American Medical Systems	AMS Perigee Vault Suspension System	1. AMS SPARC Sling System 2. AMS Monarc Sling System 3. AMS BioArc 4. AMS Large Pore Polypropylene Mesh
3/12/07	C.R. Bard, Inc.	1. Avaulta Solo Support System 2. Avaulta Plus BioSynthetic Support System	1. Bard CollaMend Implant 2. UGYTEX Dual Knit Mesh
11/8/07	Boston Scientific Corp.	Pinnacle Pelvic Floor Repair Kits	Polyform Synthetic Mesh
3/5/08	Coviden UK Manufacturing Ltd.	IVS Tunneller Placement Device	1. IVS Tunneler Intra-Vaginal Sling 2. Parietene Polypropylene Mesh 3. Surgipro Polypropylene Surgical Mesh
4/10/08	American Medical Systems	1. AMS Elevate with IntePro Lite Prolapse Repair System 2. AMS Elevate with InteXen LP Prolapse Repair System	1. AMS Pelvic Floor Repair System (Apogee/Perigee)
5/15/08	Ethicon, Inc.	1. Gynecare Prolift Total, Anterior, and Posterior Pelvic Floor Repair Systems 2. Gynecare Prolift+M Total, Anterior, and Posterior Pelvic Floor Repair Systems	1. Gynecare Gynemesh PS Prolene Soft Mesh 2. UltraPro Mesh 3. AMS Apogee Vault Suspension System 4. AMS Perigee System
8/22/08	Boston Scientific Corp.	Pinnacle Pelvic Floor Repair Kit II	1. Pinnacle Pelvic Floor Repair System 2. Prolift Pelvic Floor Repair System
9/30/08	C.R. Bard, Inc.	1. Avaulta Solo Support System 2. Avaulta Plus BioSynthetic Support System	1. Avaulta Solo Support System 2. Avaulta Plus BioSynthetic Support System
10/15/08	American Medical Systems	Apogee and Perigee Systems with PC Coated IntePro Lite	AMS Pelvic Floor Repair System

correct pelvic organ prolapse.² Hoping to improve upon known failure rates of 20% to 40% for traditional anterior colporrhaphy,^{3,4} Julian divided 24 patients presenting with a recurrent cystocele to have either another traditional colporrhaphy, or a colporrhaphy augmented with permanent synthetic mesh. After two years of follow-up, he found a recurrence rate of 0% for the mesh group, compared to 33% for the colporrhaphy group ($P < 0.05$). The ‘price’ of his success within the mesh group was a 25% rate (3 patients) of mesh-related complications consisting of erosion through the vaginal epithelium or persistent granulation tissue.

In 2001, two randomized trials were published comparing traditional colporrhaphy with and without absorbable synthetic mesh augmentation (Polyglactin 910, Ethicon, Somerville, NJ). Both trials demonstrated significantly better anatomic results, achieved while paying virtually no “price” of erosion or other mesh-related complications.^{5,6}

Later in 2001, the FDA approved the first “mesh kit” for the correction of pelvic organ prolapse in the United States (Posterior IVS Tunneller, Tyco Healthcare LP, Norwalk, CT). While initial publications regarding this device looked promising,⁷ the IVS Tunneller is now rarely used, presumably due to reports of high failure and complication rates.^{8,9} However, the IVS Tunneller remains important in the history of transvaginal “mesh kits” because it served as the “predicate” device for subsequent FDA approval of other devices under the 510(k) process. In order to understand the evolution of the commercially available vaginal mesh delivery systems, one must have a basic

understanding of the FDA’s 510(k) process (Tables 1 and 2).¹⁰

In 2002, American Medical Systems (Minnetonka, MN) introduced the Monarc Sling System as the first transobturator device approved to treat stress urinary incontinence. This device subsequently became the predicate device for the Perigee and Apogee Vault Suspension Systems, thus accelerating the evolution of vaginal mesh delivery systems.

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